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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,873	10/05/2001	John P. McKearn	CU-2559 RJS	2817

7590 08/07/2003

Mr. James M. Waner
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EXAMINER
GOLDBERG, JEROME D

ART UNIT	PAPER NUMBER
1614	11

DATE MAILED: 08/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/578,773	Applicant(s) PORTER ET AL.	
	Examiner Jerome D Goldberg	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sh t with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-103* is/are pending in the application.

4a) Of the above claim(s) *4-41,46-88 and 91-101* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,42-45,89,90,102 and 103* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 4-41 46-88 and 91-101 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Applicants state on page 6, lines 1 of paper no. 10 that " claims 40,41 46-88 and 91-101 have been cancelled without prejudice". However, these claims were not ordered by applicants to be cancelled.

With regard to applicants' remarks, the other enhanced combination would be classified in different subclasses and would support separate patents. Paper No. 9, page 2 teaches other subclasses. Therefore, the restriction requirement is deemed proper and made Final.

The Xiong et al. reference is cited to complete the record.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 42, 43, and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Reddy et al. reference taken with the Takahiko et al. reference.

The Reddy et al reference having an effective date of October 15, 1996 teaches celcoxib for treating colorectal cancer (see Ti, line 4). The Takahiko et al reference having an effective date of 1997 teaches Gemcitabine for treating solid tumor such as "lung cancer, pacreas cancer, ovarian cancer, breast cancer, renal cancer, colorectal cancer and gastric cancer" (see AB, lines 17-19). The references do not teach the ingredients together. Accordingly, one skilled in this art would find ample motivation from the prior art supra to combine the well known anti-colorectal cancer treating agents together where the results obtained thereby are no more than the additive effects of the ingredients. See In re Sussman, 1943 C.D. 518. The data in the specification is noted but fails to show an unexpected result for the combination of celecoxib and gencitabine.

Claims 44, 45, 89, 102 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Reddy et al reference and the Takaliko et al reference for the reasons fully set forth in the above rejection taken with the Aleman et al. reference.

The Aleman et al reference having an effective date of 1995 teach radiotherapy in combination with chemotherapy for treating patients with colorectal cancer. The references do not teach the combination together. Accordingly, one skilled in this art would find ample motivation from the prior art supra to combine the well know anti-colorectal cancer ingredients and radiation together where the results obtained thereby

are no more than the additive effects of the ingredients and radiation. See In re Sussman 1943 C.D. 518.

Claims 1-3, 44, 102 and 103 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific neoplasia disorders disclosed, does not reasonably provide enablement for the term "neoplasia disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The term "neoplasia disorder in claims 1-3, 44, 102 and 103 lacks clear exemplary support in the specification as filed.

Enablement is considered in view of the Wands factors (MPEP 216.01 (a). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary all of the wands factors have been considered with regard to the instant claims, with most relevant factors discussed below.

Nature of the invention: The claims are drawn to treating neoplasia disorder a combination of celecoxib and gencitabine in a mammal.

Breath of the claims: the complex nature of the claim greatly exacerbated by breath of the claims. The claims encompass treating neoplasm's broadly in a mammal.

Guidance of the specification:

The guidance given by the specification as to how one would administer the claimed compounds to a subject in order to treating neoplasm's broadly. The guidance provide

by the specification is directed to specific cancer in a specific concentration of the claimed compounds.

Working examples; all the working examples provided by the specification are directed to specific cancers.

State of the art: while the state of the art is relatively high with regard to treatment of specific cancers, the state of the art with regard to treating cancer or neoplasm's broadly is underdeveloped. In particular, there is no known anticancer agent, which is effective against all cancers. The Carter et al. reference clearly teaches that for the forty known anticancer agents, none are effective against all cancers. (see pages 362-365 of Carter et al reference).

Predictability of the art: the lack of significant guidance from the specification or prior art with regard to the actual treatment of all cancers or neoplasm's in a mammal including humans subject with the claimed compounds makes practing claimed invention unpredictable.

The quantity of experimentation necessary:

Applicants fail to provide guidance and information to allow the skilled artisan to ascertain which particular type of cancer the claimed anticancer agent is effective against without undue experimentation. The limited disclosure of several cancer is noted but will not support all cancers being claimed. The Carter et al reference shows data on twenty-three types of cancer. Applicants should at least these types of cancer with the claimed anticancer agent. The reference further teaches what is needed for employ an in vitro system to be useful in a clinical application see page 342, Table 1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerome D. Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday through Thursday from 9 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JEROME D. GOLDBERG
PRIMARY EXAMINER

Goldberg/LR
July 16, 2003